the active participation of the State/UT Governments, NGOs and other institutions.

Increase in child mortality rate in Andhra Pradesh

52. SHRI M.V. MYSURA REDDY: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Child Mortality Rate between the age group of 0-4 years in Andhra Pradesh has gone up since 2004 from 13.8 to 15.2;

(b) whether it is also a fact that there has been a fluctuation in Maternal Mortality Rate in the State between 1997-98 and 2005-06;

(c) if so, the reasons behind (a) and (b) above; and

(d) what steps Government is taking to contain the MMR and CMR in the State?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) to (d) As per the Sample Registration Survey (SRS) of the Registrar General of India, the estimated Child Mortality Rate (CMR) for Andhra Pradesh for the year 2004 is 13.8 and for the year 2006 is 15.2 and for the year 2007 is 14.6 which is given in the Statement-I (*See* below).

The estimated Maternal Mortality Ratio (MMR) for Andhra Pradesh for the periods 1997-98; 1998-2001 and 2001-03 are 197; 220 and 195 respectively. The MMR for the subsequent period is not available.

The CMR and MMR are estimated by the Registrar General of India, using statistical sampling techniques for figures across years are to be seen with reference to the confidence interval of the estimates. The fluctuations in MMR for the State of Andhra Pradesh are within this range.

The MMR statement of Andhra Pradesh as per the Registrar General of India is annexed as Statement-II (*See* below).

The National Rural Health Mission (NRHM) and the Reproductive and Child Health Programme Phase II under its umbrella, launched by the Government of India in the year 2005, in order to improve the availability of and access to quality health care including services for maternal and child health, seek to provide effective health care to rural population throughout the country.

In order to bring about a reduction in MMR and CMR, the Government of Andhra Pradesh is implementing the following key interventions, which *include:*

Maternal Health Care Services:

Maternal Health Care Services are being provided to the pregnant women by implementing the following schemes / interventions to strengthen the Maternal Care and reduce the Maternal Mortality Ratio.

- Accredited Social Health Activitist (ASHA)
- FRUs strengthened with CEMONC services (Comprehensive Emergency Obstetric and Neo-natal Care)
- Blood Bank and Blood Storage Centres
- 24-hrs Mother & Child Health Centres
- Janani SurakshaYojana.

Child Health Care Services:

Child Health Care Services are being provided to the Infants and Children by implementing the following schemes / interventions:

- Vaccine Preventable Diseases
- Implementation of Universal Immunization Program
- Convergence with Women and Child Development and DRDA departments for implementation of health activities
- Neo-natal intensive care units.

Public Private Partnership Initiatives:

- Rural Emergency Health Transportation Scheme (EMRI) - 108: Scheme to enable the rural poor to have easy access to the hospital health care services free of cost in times of emergency particularly in respect of maternal and neonatal / infant health emergencies.

Health Information Helpline - (104):

- Scheme is to provide Health Information advice, counseling to the public on Toll free No. 104.

Tribal Health Services:

- 92 Mobile Medical Units are functioning in all the tribal areas to provide the services at the doorstep of the tribal people.
- Birth waiting homes in Tribal areas are being constructed to enable women from distant and interior habitations to reach the delivery care institution a couple of days before the expected date of delivery as to prevent the complications of arrival in late labor.

Nutrition Programme for Pregnant women & Mother in convergence with Rural Development Department:

- In Indira Kranthi Patham (formerly Velugu) project, the poor of Andhra Pradesh are beginning to see improvements in their livelihoods. This is achieved *via* self-managed institutions of the poor, self-help groups, savings and credit schemes, market linkages, extension services and community infrastructure.

Statement-I

The estimated Child Mortality Rate in Andhra Pradesh, India and States

Sl. No.	India/Major States	Child Mortality Rate (0-4 years)														
		Total					Rural					Urban				
		2003	2004	2005	2006	2007	2003	2004	2005	2006	2007	2003	2004	2005	2006	2007
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
1.	Andhra Pradesh	15.2	13.8	14.8	15.2	14.6	17.3	16.2	17.3	18.3	17.1	8.3	7.9	8.8	8.3	8.7

Note: Child mortality in the age group 0-4 years is expressed as a rate per 1000 children surviving to 12 months of age only and is the probability of a child dying between 1st and 5th birthday.

SOURCE: Registrar General of India.

Statement-II

The Maternal Mortality Ratio of Andhra Pradesh

(Per 1,00,000 live births)

State	1997-98	1999-01	2001-03
Andhra Pradesh	197	220	195

SOURCE: Registrar General of India.

Clinical trials in Andhra Pradesh

53. SHRI M.V. MYSURA REDDY: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that there is no monitoring mechanism at the Central or State level to oversee the clinical tests in the State of Andhra Pradesh;

(b) if so, the reasons therefor;

(c) whether it has come to the notice of his Ministry that in the name of bio-equivalance or bio-availability tests, the pharmaceutical companies are carrying out clinical tests on innocent people which are resulting in even death of some people in Andhra Pradesh; and

(d) if so, what action his Ministry has taken on such pharma companies?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) Regulation of clinical trials comes under the purview of Central Drugs Standard Control Organization (CDSCO), Dte. General of Health Services and monitoring mechanism exists at Central level. Guidelines and requirements for conducting clinical trials in the country are specified in Schedule-Y of Drugs and Cosmetics Rules, 1945 and it requires that the clinical trial is carried out as per Indian Good Clinical Practices (GCP) Guidelines issued by Dte. General of Health Services.

Before conduct of clinical trial the investigator is also required to give undertaking that he will maintain adequate, accurate records and make those records available for audit / inspection (Oversee) by the sponsor, Ethics Committee, Regulatory Authority or their authorized representatives.

As per clause 3.1.13 of Indian GCP guidelines the sponsor should ensure that clinical studies are adequately monitored and they must appoint adequately trained monitor to supervise the clinical trial.

Further, clause 3.1.14 of said guidelines requires that sponsor should perform audit as a part of Quality Assurance system. Auditor should document their observations which should be made available to the Regulatory Authorities when called for.

(c) and (d) Bio-equivalence / Bio-availability studies of new drugs are permitted to be carried out in the country in accordance with the Drugs and Cosmetics Rules. The studies are required to be conducted as per the GCP guidelines.